K081637

510(k) Summary

as required by 807.92

JUL - 1 2008

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan

2. Submitter's Name and Address

Koji Matsushima (Mr.)
General Manager
Regulation Management Division
Quality Assurance Center
2970 Ishikawa-machi, Hachioji-shi, Tokyo 192-8505, Japan
Telephone: 81-42-660-9607
Fax: 81-42-660-9588

3. Date of Submission

June 6, 2008

4. Device Trade Name

LASER IMAGER, DRYPRO MODEL 873

5. Common Name

Medical Image Hardcopy Device

6. Classification

Class Ⅱ, 21 CFR 892. 2040, Medical image hardcopy device

7. Product Code

90 LMC

8. Predicate Device

DRY LASER IMAGER, DRYPRO MODEL 793, 510(k) Number: K042133

9. Description of Device

The LASER IMAGER, DRYPRO MODEL 873 is a Medical Image Hardcopy Device to acquire images from diagnostic equipment such as CT, MRI, DSA or Full Field Digital Mammography System and print them on medical dry-film.
The device consists of film supplying unit, film transferring unit, exposing unit, heat-developing unit, operating unit, power supplying unit and main control unit.
This product employs semiconductor laser for laser scanning and it complies with the Federal Performance Standard 21 CFR Part 1040.10.

10. Indications for Use

The LASER IMAGER, DRYPRO MODEL 873 is intended to be used to acquire images from diagnostic equipment such as CT, MRI, DSA or FDA-approved Full Field Digital Mammography System and print the images on medical dry-film.
The devices are intended to be used by trained medical personnel in a clinic or hospital environment.

11. Substantial Equivalence to Predicate Device

The LASER IMAGER, DRYPRO MODEL 873 is substantially equivalent to our DRY LASER IMAGER, DRYPRO MODEL 793, 510(k) Number: K042133. Comparison of the principal characteristics is shown in the Section 2.

12. Compliance Standard

Safety standard : IEC60601-1 Ed.2(1988)+ A1(1991)+A2(1995)
Electromagnetic Compatibility : IEC60601-1-2 Ed.2(2001)+A1(2004)
Radiation safety : 21 CFR 1040.10, IEC60825-1(1993)+A1(1997)+A2:2001
DICOM

13. Conclusion

The LASER IMAGER, DRYPRO MODEL 873 has the same intended use and basically the same technological characteristic as the predicate device which is approved 510(k) number: K042133. This Special 510(k) has demonstrated substantial equivalence as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2008

STORCH, AMINI, & MUNVES, P.C.
% Mr. Koji Matsushima
General Manager
Konica Minolta Medical & Graphic, Inc.
Regulatory Management Division, Quality Assurance Center
2970 Ishikawa-machi, Hachioji-shi
192-8505 Tokyo
JAPAN

Re: K081637
Trade/Device Name: Laser Imager, Drypro Model 873
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: June 6, 2008
Received: June 11, 2008

Dear Mr. Matsushima:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) :

Device Name : LASER IMAGER, DRYPRO MODEL 873

Indications for Use:

The LASER IMAGER, DRYPRO MODEL 873 is intended to be used to acquire images from diagnostic equipment such as CT, MRI, DSA or FDA-approved Full Field Digital Mammography System and print the images on medical dry-film.
The devices are intended to be used by trained medical personnel in a clinic or hospital environment

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081637